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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,470	12/18/2001	Petr Jakovlevich	CU-2642 RJS	4248

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Richard J Streit
Ladas & Parry
Suite 1200
224 South Michigan Avenue
Chicago, IL 60604

EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	6

DATE MAILED: 04/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/936,470	Applicant(s) JAKOVLEVICH ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application (Russian Federation 9910666, filed on March 16, 1999) under 35 U.S.C. 119(a)-(d). However, the certified copy and translation of the priority document have not been received.

The first paragraph of the specification fails to refer to the PCT parent application.

Claim Rejections—35 USC § 112, 1st paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 6-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a genetically engineered interferon, polyvinyl pyrrolidone and/or polyethylene oxide, and Trilon B does not reasonably provide enablement for a composition comprising any other biocompatible polymers or any other antioxidants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining whether a disclosure satisfies

enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 6-8 are drawn to a composition comprising a recombinant interferon, a biocompatible polymer, and an antioxidant. As written, these claims encompass any composition as long as it comprises these elements and the viscosity of the composition is within 11-300 Pa*s. Claims 9-13, while narrower when compared with Claims 6-8, are still very broad; each of the claims either covers any biocompatible polymers or any antioxidants. However, the specification merely discloses making and using of a composition comprising a genetically engineered interferon, polyvinyl pyrrolidone and/or polyethylene oxide, and Trilon B. There are no working examples of making and using any other polymers or antioxidants. Furthermore, the disclosure fails to provide sufficient guidance and information on how to make and use a composition comprising any other polymers and or antioxidants. The state of the art is such that it is unpredictable whether a given biocompatible polymer or antioxidant will, together with an interferon, form an antiviral liquid drug. For example, an antioxidant agent may have a toxic effect (See, e.g., last paragraph of column of 2, U.S. Patent No. 4,710,376, December 1, 1987).

In view of these factors, it would require undue experimentation for one skilled

in the art to make and use the composition embraced by the instant claims.

Claim Rejections—35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 6, 7, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cymbalista (U.S. Patent NO. 4,647,454, March 3, 1987) in view of Evans et al. (U.S. Patent No. 4,710,376, December 1, 1987) and Gray and Rinderknecht (U.S. Patent NO. 4, 855,238, August 8, 1989).

Cymbalista teaches a stable interferon β composition comprising 0.5%-10% (weight/volume) of polyvinyl pyrrolidone, a biocompatible polymer (See, e.g., Claim 1). Since Variant 3 disclosed in the preferred embodiments comprising 5% (0.05g/ml) polyvinylpyrrolidone, which yields the viscosity of the composition 11 Pa*s (See instant disclosure, page 5), the interferon β composition comprising 0.5%-10% of polyvinyl pyrrolidone taught by Cymbalista would be reasonably be expected to yield viscosity in the range of 11-300 Pa*s. Since interferon β has antiviral effects and the viscosity is within the range of 11-300 Pa*s, the composition taught by Cymbalista would be suitable as a nasal drop formulation.

Cymbalista fails to teach the use of recombinant interferon, an antioxidant, and the polymer of polyethylene oxide.

Evans et al. teach a topical therapeutic composition comprising a recombinant interferon, an oxidation inhibitor system (an antioxidant) and polyethylene glycol, i.e., polyethylene oxide (See, e.g., claims 1-5).

Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a recombinant interferon and a biocompatible polymer, polyethylene glycol, and to include an antioxidant in the composition taught by Cymbalista. One would be motivated to do so because (1) a recombinant interferon, for example, interferon β, has enhanced stability and activity as taught by Gray and Rinderknecht (last paragraph of column 2); (2) an interferon is susceptible to oxidative degradation and an oxidation inhibitor (an antioxidant) will inhibit such oxidative degradation as taught by Evans et al. (See, e.g., column 2, 4th paragraph and claims 1, 2, and 8); and (3) polyethylene glycol is a biocompatible polymer which has been used in topical therapeutic composition as taught by Evans et al (column 17, Example 5). In addition, since polyvinyl pyrrolidone and polyethylene oxide fulfill the same function in the composition as discussed above, it would have been an obvious matter of choice to use either one polymer or both.

Claim Objection

6. Claim 10, 12, and 13 are objected to because of a typographical error, "polyvinilpyrrolidone" should be polyvinyl pyrrolidone. Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Ruixiang Li
Examiner
April 3, 2002